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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,615	07/08/2003	Clemens Hendricus, M. Kocken	2183-6041US	8276
24247	7590	07/10/2007		
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			EXAMINER HIBBERT, CATHERINE S	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 07/10/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/615,615	Applicant(s) KOCKEN ET AL.	
	Examiner Catherine S. Hibbert	Art Unit 1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8-10, 12, 15-23, 25-30, 32, 33, 35-37, 39, 42, 43, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 12, 15-23, 25, 26, 32, 33, 35-37, 39, 42 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-10, 27-30, 46 and 47 is/are rejected.
- 7) ☒ Claim(s) 6, 8, 27, 46 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/2/2007, 4/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Please note the Examiner for this Application No. 10/615,615 has changed.

Receipt is acknowledged of a response, filed 2 April 2007, amending claims 1-4, 6, 8-10, 27-30 and adding new claims 46-47. Claims 1-4, 6, 8-10, 12, 15-23, 25-30, 32, 33, 35-37, 39, 42, 43, 46 and 47 are pending. Claims 5, 7, 11, 13-14, 24, 31, 34, 38, 40-41, 44-45 are cancelled. Claims 12, 15-23, 25, 26, 32, 33, 35-37, 39, 42 and 43 are withdrawn to non-elected subject matter. Claims 46-47 are new.

All objections/rejections not repeated herein are hereby withdrawn. Where applicable, a response to Applicant's arguments will be set forth immediately following the body of any objections/rejections repeated herein. As no new grounds of rejections are set forth that are not necessitated by material changes to the claims this action is made FINAL.

Claim Objections

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 is drawn to the method of claim 1 and further recites the limitation "wherein said mRNA encoding Plasmodium AMA-1 ectodomain belongs to the clade whose members express AMA-1 protein as an approximately 83 kDa protein". While this claim was further limiting to a

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previous version of claim 1 which recited the broader term, "Plasmodium", claim 6 is not further limiting to the amended version of claim 1 which recites "Plasmodium falciparum", since Plasmodium falciparum "belongs to the clade whose members express AMA-1 protein as an approximately 83 kDa protein" (instant specification paragraph bridging p. 2-3). Appropriate correction is required.

Claim 8 is objected to because of the following informalities: Claim 8 is dependent on Claim 6 which is objected to above. Appropriate correction is required.

Claim 27 is objected to because of the following informalities: Claim 27 is missing a period at the end of the sentence. Appropriate correction is required.

Claims 46 and 47 are objected to because of the following informalities: The term "falciaparum" appears to be a typographical error for the term "falciparum". Appropriate correction is required.

Response to Applicant's Arguments

The 102(b) rejection stated in the Office Action filed 2 October 2006 has been overcome by Applicant's amendment to claims and persuasive argument that the Kocken et al (Infection & Immunity, Jan 1999, p.43-49, made of record in References Cited, 17 May 2005) "fails to describe, either expressly or inherently, a *Plasmodium falciparum* sequence or the sequence depicted in FIG. 1" (Applicant's Response p.9).

The 103(a) rejection stated in the Office Action filed 2 October 2006 has been overcome by Applicant's amendment to claims and persuasive argument that the

primary reference, Kocken et al "fails to describe, either expressly or inherently, a *Plasmodium falciparum* sequence or the sequence depicted in FIG. 1" (above). In addition, Applicant's argument that the secondary reference, Withers-Martinez et al, (Protein Eng. 1999; 12(12):1113-20, made of record in References Cited, 17 May 2005) does not teach or suggest the AMA-1 protein in native conformation produced by the Pichia cells and furthermore that the reference teaches away from that result stating "Withers-Martinez specifically states that the protein produced by the Pichia cells accumulates in insoluble form in the yeast cells" (Applicant's Response p.10) is also found persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6, 8-10, 27-30, 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 27, 46 and 47 recite the term "parts spanning from amino acid residue 25-442, 97-318, 97-442, and 97-545" in lines 5-6. It is unclear whether this term requires selection from the group consisting of an amino acid sequence consisting of the contiguous amino acid residues 25-442, 97-318, 97-442 and 97-545 or, alternatively, whether this term includes all amino acid sequences which begin at amino

acid residues 25 or 97, for example, and have an undefined ending amino acid residue, or, alternatively, whether this term refers to *any part* of the stretches of amino acid sequences: 25-442, 97-318, 97-442 and 97-545, which could reasonably read on a single amino acid. Therefore, the metes and bounds of the claims are indefinite.

Claims 1, 27, 46 and 47 recite the term “wherein said *Plasmodium falciparum* AMA-1 ectodomain exhibits specificity for mAB 4G2”. However, since the claims are drawn to a “functional part” of an ectodomain, it is unclear whether only the ectodomain from which the functional part is derived is required to show specificity for mAB 4G2 or if the “functional part” of the ectodomain that is present in the invention is also required to exhibit specificity for mAB 4G2. Therefore, the metes and bounds of the claims are indefinite.

Claims 1, 27, 46 and 47 refer to specific amino acid residue numbers but the claims do not provide amino acid residue numbers in FIG 1 to correlate to these claims. Because the claims are limited by the amino acid residue number and not by the nucleotide sequence number, it is unclear whether the invention requires specific contiguous stretches of the nucleotide sequence of FIG. 1 or whether the claim limitation is directed only to any nucleotide sequence which encodes specific contiguous stretches of the *amino acid sequence* shown in FIG 1. Therefore, the metes and bounds of the claims can not be determined and claims are properly rejected.

Claims 46 and 47 recite the limitation "the nucleotide sequence encoding the functional part thereof of FIG. 1" in lines 7. There is insufficient antecedent basis for this limitation in the claims.

Claims 2-4, 6, 8-10, and 28-30 are indefinite insofar as they depend from claims 1 and 27 above.

State of the Prior Art

Lanar et al in "*Plasmodium Falciparum* AMA-1 Protein and Uses thereof" [US PGPub No. 2006/0264619A1, which claims priority to US Provisional Application 60/278,616, filed 26 March 2001] teaches a method for producing the ectodomain of the AMA-1 protein from the *P. falciparum* (3D7 strain) spanning amino acid residues 75-524 for use in eliciting antibodies in the field of malaria vaccines. While the US PGPub No. 2006/0264619A1 contemplates the use of modified AMA-1 sequence incorporating *E.coli* codon bias and suggests several host cell types including yeast cells (§ 70), lines 1-4), these limitations are not contemplated in the US Provisional Application 60/278,616. Lanar et al fails to teach the nucleic acid structure of the instant application and 60/278,616 fails to teach expressing the *P. falciparum* AMA-1 in yeast cells and fails to teach the use of yeast cell codon bias for optimization of the expression of yeast cell translation products as recited in the instant application.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Hibbert whose telephone number is 571-270-3053. The examiner can normally be reached on Monday-Friday, 7:30 AM-5:00 PM, ALT. Friday, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,

Catherine S. Hibbert/AU1636


DAVID GUZO
PRIMARY EXAMINER